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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,991	11/12/2003	Gabriel Pulido-Cejudo	50499-1A	6527

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NATIONAL RESEARCH COUNCIL OF CANADA
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CANADA

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/705,991

Applicant(s)

PULIDO-CEJUDO, GABRIEL

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9 and 10 is/are rejected.
- 7) ☒ Claim(s) 4, 11, 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 4, and 9-12 are pending and under consideration.

Specification

The disclosure is objected to because of duplicate pages numbers. Pages 16-20 after first occurrence of Page 20 should be renumbered to 21-26. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 9 and 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The specification at page 4, 3rd full paragraph discloses that the estrogen-stimulated isoenzyme of leucine aminopeptidase claimed in claim 1 and 4 has only one molecular weight, which is "315" kDa as in claims 9 and 11. Therefore the molecular weight is the inherent characteristics of the antigen in the respective base claims.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102, Withdrawn

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Gupta et al., IDS, Indian J Pathol Microbiol, 1989 Oct;32(4):301-5 is withdrawn because Gupta does not use immunoassay for detection of the leucine aminopeptidase.

Claim Rejections - 35 USC § 103, Maintained

Claims 1, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al (cited above) in view of Deng et al (IDS, 1996, Hepatology, vol. 23, pages 445-453).

Claim 1, 9 and 10 are drawn to a method of breast cancer diagnosis by detecting estrogen stimulated aminopeptidase by immunoassay.

Applicant argues that Gupta measures the aminopeptidase activity by chemical method, not immunoassay, and Deng merely teaches an antibody to a serum aminopeptidase, and the instantly claimed method is much more sensitive (as disclosed at Table 3 at page 16 and Example 5) than the method of Gupta.

These arguments have been fully considered but found not persuasive. The specification at Example 5, and data disclosed at Table 3 is about enriching the antigen (i.e. the aminopeptidase) using the antibody (most likely the one in the instant claim 4), followed by LAPase activity similar to the assay used by Gupta. The sensitivity results from enriching, therefore more aminopeptidase molecules to convert the substrates to products. However, claim 1 does not say anything about the enriching step as disclosed in Example 5 of the specification. Therefore, applicant argument with the data disclosed at Table 3 is considered as an argument with a limitation not present in the claim. The specification at page 7, last full paragraph reasonably indicates that the

Art Unit: 1642

limitation "an immunoassay" means direct detection of immune complex between an antigen and an antibody. The specification does not appear to say that "an immunoassay" encompasses enriching an antigen with an antibody bead, followed by the chemical method of detection as disclosed at Table 3. Further, it is not clear if using any antibody other than the monoclonal antibody in claim 4 could enrich the estrogen-stimulated isoenzyme of leucine aminopeptidase. As the molecular weight in the new claims, it appears that it is the inherent molecular weight of the serum aminopeptidase in breast cancer patient. Note Example 5 of the specification.

Allowable Subject Matter

Claims 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


Art Unit: 1642

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642